REMARKS

After entry of this amendment, claims 1-5, 7-9 and 26-27 are pending. New claim 27 has been added and finds support, *inter alia*, in the original claims. Claims 1 and 2 have been amended without prejudice or disclaimer and finds support *inter alia* in the original claims. Claim 1 finds further support in the specification at page 14, lines 25-29. Claim 2 finds further support at page 15, lines 6-9. No new matter has been added.

Claim Rejection – 35 USC § 112

Claims 1-5, 7-9 and 26 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement and for alleged lack of an enabling disclosure. Applicants respectfully disagree. However, to expedite prosecution, claims 1 and 2 have been amended without prejudice or disclaimer to recite the nucleotide sequences with more specificity. Applicants respectfully request reconsideration in light of the present amendment and for the following reasons.

Written Description Rejection

The Examiner maintains the position that only very limited number of genes encoding Δ-5- and Δ-8-desaturases are disclosed in the prior art and Δ-9-elongase was not well known in the art at the time of filing. The Examiner concludes that Applicants were not in possession of a method using any Δ-5-desaturase, Δ-8-desaturase and Δ-9-elongase. Applicants respectfully disagree that the claims as amended are not described.

As amended, claim 1 specifies the amino acid sequences of the Δ-5-desaturase, Δ-8-desaturase and Δ-9-elongase and claim 2 specifies the nucleotide sequences that encode the Δ-5-desaturase, Δ-8-desaturase and Δ-9-elongase. It is respectfully submitted that the specification provides sufficient written description for the claimed genus as defined by the amended claims.

As to new claim 27, the Δ-8-desaturase and Δ-9-elongase are defined by their specific amino acid sequence. With regard to Δ-5-desaturase, as disclosed in the specification and discussed in the Amendment and Reply Under 37 CFR § 1.111 dated November 9, 2007, Δ-5-desaturases are well known in the art at the time of filing. Additionally, the specification provides 3 species of Δ-5-desaturases (SEQ ID NOs: 6, 8, and 10). It is respectfully submitted

that the specification, together with the existing knowledge in the particular field and the extent and content of the prior art, satisfies the written description requirement as to the genus of nucleotide sequences encoding Δ-5-desaturases. See *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

Reconsideration and withdrawal of this rejection is respectfully requested in light of the present amendment and the above remarks.

Enablement Rejection

The Examiner further rejects the claims based on the specification allegedly not being enabling for any transgenic plant expressing any Δ-5-desaturase, any Δ-8-desaturase, and any Δ-9-elongase. Applicants respectfully disagree.

As amended, claims 1-5, 7-9 and 26 recite Δ-5-desaturase, Δ-8-desaturase, and Δ-9-elongase by their specific amino acid sequence. Accordingly, it is respectfully submitted that the specification is enabling for the claims as now presented.

With regard to claim 27, as discussed above, Δ-5-desaturases are well known in the art at the time of filing. Furthermore, as disclosed in the specification, Δ-5-desaturases may be modified by substitution, inversion, insertion or deletion of one or more amino acid residues while retaining the desired function. See page 19, lines 1-9. For instance, such a modification can be realized by replacing one amino acid with another amino acid having similar physicochemical properties (*e.g.*, bulk, basicity, or hydrophobicity). See page 19, lines 22-25. From this guidance, a person skilled in the art would be directed to mutations which are not likely to impair function. Methods of generating such mutations, for example, site-direct mutagenesis and PCT-mediated mutagenesis, are standard techniques readily available and known to those skilled in the art. The need for routine screening to confirm function is normal in the art and not undue experimentation.

Furthermore, the assays useful for determining the enzymatic activity of the structural genes are known in the art. For instance, Browse *et al.* (US 6,825,017) describes the assays suitable for determining Δ-5-desaturase activity. See Browse, Col. 6, lines 58-64. Moreover, Examples 5, 6 and 7 provide methods for generating transgenic plants expressing structural genes and Examples 10 and 11 provide methods for analyzing fatty acids compositions in such

transgenic plants. Taken together, it is respectfully submitted that one skilled in the art would recognize that screening and testing for Δ-5-desaturase activity is routine and not undue experimentation. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine"). It is further submitted that the detailed guidance provided in the present specification and the routine nature of the screening and testing overcome the unpredictability alleged by the Examiner.

In view of the existing knowledge and the state of the art, the detailed description, guidance, and working examples provided in the specification, and high level of skill, there is no reason to doubt operability of the process as claimed in claim 27 using any functional Δ-5-desaturase. On these facts, an analysis under *In re Wands* supports enablement.

The Examiner further maintains the position that the specification allegedly not showing production of compounds encompassed by the formula I of claim 1 other than C16, C18 and C20 polyunsaturated fatty acids as illustrated in Table 1. Applicants respectfully disagree and traverse the rejection.

As discussed above, the specification provides working examples on how to generate transgenic plants expressing the structural genes and how to analyze fatty acids compositions in such transgenic plants. Thus, the specification provides not only examples, but also sufficient guidance for one skilled in the art to generate expression constructs, to produce transgenic plants, and to express the construct resulting in the production of the desired polyunsaturated fatty acids in plants. By focusing primarily on C16, C18, and C20 polyunsaturated fatty acids, Table 1 is designed to demonstrate the enzymatic specificity of Δ-5-desaturase, Δ-8-desaturase, and Δ-9-elongase in the transgenic plants. Accordingly, compounds shown in Table 1 are representative of the compounds encompassed by the formula I of claim 1 with the defined meanings of n, m, and p, and should not be a basis to limit the scope of the claims. Additionally, there is no requirement that every species of the compounds be disclosed.

For at least the above reasons and in light of the present amendment, it is respectfully submitted that the claims recite a scope of subject matter which a skilled artisan could clearly make and use according to the teaching in the specification. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Accompanying this response is a two-month extension of time to and including January 20, 2009 to respond to the Office Action mailed August 20, 2008 with the required fee. No further fee is believed due. However, if any additional fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 13478-00001-US from which the undersigned is authorized to draw.

Respectfully submitted,

By /s/ Hui-Ju Wu
Hui-Ju Wu, Ph.D.
Registration No.: 57,209
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P. O. Box 2207
Wilmington, Delaware 19899-2207
(302) 658-9141
(302) 658-5614 (Fax)
Agent for Applicants

#633409